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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,845	10/15/2003	Michael T. Lotze	076333-0393	9535

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EXAMINER	
JUEDES, AMY E	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
04/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/688,845	LOTZE ET AL.	
	Examiner	Art Unit	
	AMY E. JUEDES	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31 and 36-40* is/are pending in the application.

4a) Of the above claim(s) *1-26,30 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-29, 31, 35-38, and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and remarks, filed 1/18/08, are acknowledged.

Claim 27 has been amended.
Claims 36-40 have been added.
Claims 1-31 and 35-40 are pending.

Claims 1-26 and 30 stand withdrawn from further consideration, and new claim 39 is withdrawn, pursuant to 37 CFR 1.14209 as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Claims 27-29, 31, 35-38 and 40 are under examination.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 27-29, 31, and 35 stand rejected, and claims 36-38 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Bhardwaj et al., 1996, as evidenced by Hackstein et al., 2002.

As set forth previously, Bhardwaj et al. disclose a culture (i.e. a composition) comprising ex-vivo purified dendritic cells and IL-12 (see pg. 715 and Table 1 in particular). As evidenced by Hackstein et al., dendritic cells arise from CD34+ stem cells, and thus the ex-vivo isolated dendritic cells taught by Bhardwaj et al. are CD34+ derived. It is noted that the term "therapeutic composition" carries little patentable weight in the absence of evidence of a structural difference, since it refers to an intended use of the composition. The culture medium taught by Bhardwaj et al. (RPMI supplemented with gentamicin, human serum and HEPES buffer) is not incompatible with biological activity and therefore meets the limitations of a "therapeutic composition".

Applicant's arguments filed 1/18/08 have been fully considered, but they are not persuasive.

Applicant argues that Bhardwaj et al. do not teach a "therapeutic composition", which is a composition formulated to be administered to a subject. Applicant contends that the cell cultures taught by Bhardwaj et al. are generated for basic

research purposes and are not formulated to be administered to a subject.

The term "therapeutic" composition refers to an intended use the claimed composition. If the body of the claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. See MPEP 2111.02. In the instant case, the claims set forth a composition comprising a physiologically or pharmaceutically acceptable solution, a dendritic cell, and IL-12. Bhardwaj et al. teach a composition comprising tissue culture medium (i.e. a physiologically or pharmaceutically acceptable solution), dendritic cells, and IL-12. Thus, the composition of Bhardwaj et al. is structurally identical to the claimed composition. Furthermore, cells in culture are considered to be compatible with physiological conditions and not incompatible with pharmaceutical use. In fact, the specification on page 18 specifically states that the use of conventional media as a formulation for administration is contemplated, as long as said media is not incompatible with an active compound of the invention. Clearly, culture media is not incompatible with dendritic cells (i.e. the active compound) since dendritic cells are optimally grown and expanded in said media. The only evidence provided by Applicant as to the fact that tissue culture medium does not meet the limitation of a "therapeutic" composition is the declaration of Inventor Lotze. Said declaration states that cell cultures might contain impurities or inhibitory proteins such as IL-10 or TGF-β, that may cause a reaction in a patient. However, even if present in the cell cultures, cytokines such as IL-10 or TGF-β would not render a solution to be physiologically incompatible. In fact, dependent claim 31 specifically states that the therapeutic composition can comprise TGF-β or IL-10.

4. Claim 27-29, 31, and 35 stand rejected, and claims 36-38 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Kelleher et al., 1998.

As set forth previously, Kelleher et al. disclose a culture (i.e. a composition) comprising dendritic cells and IL-12 (see pg. 750 in particular). Kelleher et al. further teach that said dendritic cells are derived from CD34 bone

marrow stem cells (see abstract and pg. 750 in particular). It is noted that the term "therapeutic composition" carries little patentable weight in the absence of evidence of a structural difference, since it refers to an intended use of the composition. The culture medium taught by Kelleher et al. (RPMI supplemented with penicillin, streptomycin, glutamine, FCS, and 2 mercaptoethanol) is not incompatible with biological activity and therefore meets the limitations of a "therapeutic composition".

Applicant's arguments filed 1/18/08 have been fully considered, but they are not persuasive.

Applicant argues that Kelleher et al. do not teach a "therapeutic composition", which is a composition formulated to be administered to a subject. Applicant contends that the cell cultures taught by Kelleher et al. are generated for basic research purposes and are not formulated to be administered to a subject.

It is the Examiner's position that cells in culture are considered to be compatible with physiological conditions and meet the limitations of a therapeutic composition for the same reasons set forth about.

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are

unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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